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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,517	02/12/2004	Edward Roydon Jost-Price	50164/026005	6701

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CLARK & ELBING LLP
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EXAMINER	
PACKARD, BENJAMIN J	
ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
01/13/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/777,517	JOST-PRICE ET AL.	
	Examiner	Art Unit	
	Benjamin Packard	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,24-26,28,30-50 and 66-86* is/are pending in the application.

4a) Of the above claim(s) *1-21,24,31-44,66-80 and 82-86* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25,26,28,30,45-50 and 81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4pg (9/22/08)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed 09/22/08, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 25-26, 28, 30, and 45-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Kumar et al (Postgraduate Medical Journal, 78, 921 (2002) 439-440).

Kumar et al discloses a 60 year old man who was administered 10mg prednisolone once daily and 20mg paroxetine once daily.

Where the administration of both is daily, the dosage regimen appears to read on the instant claim limitation of simultaneous administration.

Note, the instant claims are directed at treating a patient diagnosed with or at risk of developing an immunoinflammatory disorder. Where all people are “at risk” of developing an immunoinflammatory disorder, it would appear any administration of the two compounds reads on the instant claims.

Further note that the specification defines "high" and "low" (instant spec at pg 9) so generally that the prior art is viewed as reading on the same.

Claim 81 is rejected under 35 U.S.C. 102(b) as being anticipated by Franklin (Seminars in Arthritis and Rheumatism, Vol 29, No 3 (1999) 172-182).

Discloses a patient was treated first with DMARDs after being diagnosed with rheumatoid arthritis, then with paroxeinte (Pg 176, Case 1).

Note, where the method only requires the compounds be administered to a patient in need thereof (afflicted with rheumatoid arthritis), this method is reasonably expected to inherently be met, given the same drugs are administered to the same patient population.

While examination has not expanded beyond the elected species and elected disease, the following rejection is made to further prosecution with regards to the claims which read on the elected species and the following prior art is used elsewhere.

Claim 25-26, 28, 30, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Sandyk (Intern J Neuroscience, Vol 98 (1999) 83-94).

Sandyk teaches a woman was treated from June 1998 to October 1998 with paroxetine for depression and treated in August of 1998 with high doses of oral prednisone to treat sensorineural hearing loss for a week (pg 85 lines 2-8).

Note, the instant claims are directed at treating a patient diagnosed with or at risk of developing an immunoinflammatory disorder. Where all people are "at risk" of

developing an immunoinflammatory disorder, it would appear any administration of the two compounds reads on the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Claims 45 and 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al (Postgraduate Medical Journal, 78, 921 (2002) 439-440).

Kumar et al is discussed above, but does not disclose the administration regimen.

Where the drugs are disclosed to be concurrently medicated, it would be obvious to one of ordinary skill in the art to administration the drugs simultaneously, given the convenience for patients taking concurrent medications.

Claims 45 and 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sandyk (Intern J Neuroscience, Vol 98 (1999) 83-94).

Sandyk is discussed above, but does not disclose the administration regimen.

Where the drugs are disclosed to be concurrently medicated, it would be obvious to one of ordinary skill in the art to administration the drugs simultaneously, given the convenience for patients taking concurrent medications.

Claims 25-26, 28, 30, 45-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sandyk (Intern J Neuroscience, Vol 98 (1999) 83-94) in view of Biedermann et al (US 5,833,998).

Sandyk is discussed above, but does not disclose the use of prednisolone.

Biederman et al discloses known corticosteroids, including prednisolone and prednisone.

It would have been obvious to one of ordinary skill in the art, when treating the patient in Sandyk to substitute prednisolone for prednisone, where a reasonable expectation of success is based on their common steroidal anti-inflammatory properties.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-R 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612